REMARKS

As noted previously, the Applicant appreciates the Examiner's thorough examination of the subject application.

Claims 1-18, 20-35, and 37 were previously pending in the application. Claims 2-7, 10-18, and 20-33 are canceled herein. Claims 2 and 8 are amended herein. New claims 43 and 44 are added. No new matter has been added.

In the non-final Office Action mailed 25 February 2008, claims 1-18, 20, 34, 35, and 37 were rejected on various statutory grounds, described in further detail *infra*. Applicant requests reconsideration and further examination of the subject application in light of the foregoing amendments and the following remarks.

Claim Rejections – 35 U.S.C. § 112

The Examiner maintained the previous rejection of claims 10 and 20 under 35 U.S.C. § 112, ¶ 2, as being indefinite. Applicant notes that claims 10 and 20 have been canceled herein rendering the rejection moot.

Claim Rejections – 35 U.S.C. § 102

In the Office Action, the Examiner maintained the previous rejection of claims 1, 9-11, 19, 20, 34, and 38-42 under 35 U.S.C. § 102(b) as being anticipated by international application WO 2000/01294 to Parker at al. ("Parker"). Applicant traverses the rejection and requests reconsideration for the following reasons.

As a threshold matter, Applicant notes that claims 1, 9-11, 19, 20, and 38-42 have been canceled, rendering the rejection under 35 U.S.C. § 102(b) moot as to these claims and leaving claim 34 as the sole claim to which the rejection still applies.

One requirement for a rejection under 35 U.S.C. § 102(b) is that the cited reference teach all the elements as arranged in the claim(s) at issue. In this situation, Parker fails to teach (or, for

that matter, suggest) each of the elements in independent claims 34, which are the base claims for the remaining claims subject to the rejection.

Independent claim 34 as amended recites the following:

A laser system for therapeutic treatment of bacteria in an infected site with non-ionizing optical energy and without detrimental heat deposition or irreversible harm to a biological system including the infected site, the system comprising:

(a) a laser oscillator system configured and arranged to selectively emit near infrared radiation at a power density in one or both of a first wavelength range of about 865 nm to about 875 nm and a second wavelength range of about 925 nm to about 935 nm;

(b) a control connected to the laser oscillator system, the control configured and arranged to control the selective emission of near infrared energy at the power density from the laser oscillator system for absorption as non-ionizing optical energy without detrimental heat deposition or irreversible harm to the biological system at the infected site;

(c) an optical channel connected to the laser oscillator system, the optical channel configured and arranged for transmission of the near infrared radiation; and

(d) a head configured and arranged to deliver the near infrared energy from the laser oscillator system and the optical channel to bacteria in the infected site at the power density for absorption at the infected site.

[Emphasis Added]

In contrast, Parker is directed to and teaches the use of a blood constituent monitor including a light transmitter and a plurality of optical fibers positioned to transmit light to a body and a light detector including a plurality of light detector fibers. See, e.g., Parker, page 5, lines 19-25.

For the rejection, the Examiner cites a specific portion of Parker as allegedly teaching the wavelength ranges as claimed by the Applicant, e.g., as in claim 34. ***In actuality, Parker teaches no such thing, as careful review of Parker reveals.*** More specifically, the Examiner contends the following for maintaining the rejection over Parker:

> In view of the specific disclosure of Parker et al at page 8, lines 10-14, wherein the entire range of between 800nm and 100nm sampled at regular intervals of 1.96nm, which would result in application of at least 4 different wavelengths in each of applicant's two claimed ranges, this argument is not convincing.
>
> [Emphasis Added]

Applicant draws the Examiner attention to the fact that Parker describes using *in vivo* testing that utilized (i) a multi-channel photodiode (MCPD) spectrophotometer, (ii) a broadband light source consisting of a 400W quartz-halogen light source, and (iii) software supplied with the MCPD spectrophotometer to "access data points at 1.94nm intervals with the wavelength range 300-1100nm." See Parker, page 9, lines 1-11. The Parker testing thus included use of a spectrophotometer and a broadband light source, with light from the source being detected by a detector with a photodiode array, which then produced test data. The software of the spectrophotometer was then used for analysis of the test data.

This is supported and corroborated by the portion of Parker cited for the rejection:

> The analysis which is presented here uses the same wavelength range used in the previous glucose studies carried out namely: 805nm, 925nm, 970nm and the broadband average 1000-1100nm, but additionally wavelength sampled at regular intervals in the entire range 800nm to 1100nm. Intervals of 1.96nm worked well.
>
> [Emphasis added]

Parker makes it clear that it is the spectrophotometer software that provides the ability to utilize the data at the "regular intervals" and not that light is supplied in discrete wavelengths exactly at these intervals:

> Using the supplied software, the instrument allows access to data points at 1.94nm intervals within the wavelength range 300-100nm. The range displayed during the glucose experiments was 500-1100nm.

Thus one skilled in the art would understand that Parker teaches "sampling" of specific optical data at regular intervals across a broad spectrum.

To reiterate the above contentions, Parker does not teach or suggest the application of laser energy at the specific narrow wavelength ranges or discrete wavelengths identified and claimed by the Applicant in the subject application for application to kill/treat bacteria at an infected site. Moreover, Parker does not appreciate or recognize the advantages of utilizing the narrow NIR wavelength ranges and discrete wavelengths for causing photodamage in bacteria as claimed by Applicant. In fact there is not a single aspect of Parker that teaches or suggests a "therapeutic nature" to the wavelengths of light that are discussed.

Thus, Parker does not teach (or suggest) each and every limitation as arranged in claim 34, and therefore is an improper basis for a rejection of the claims under 35 U.S.C. § 102(b). Because of this, Applicant respectfully requests that the rejection of claims 34 under 35 U.S.C. § 102(b) be removed accordingly.

Claim Rejection – 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-4, 9-14, 19, 20, and 34-42 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,669,466 to L'Esperance ("L'Esperance") in view the article by Neuman et al., "Characterization of Photodamage to Escheria Coli in Optical Traps," Biophy J. November 1999, pp 2865-2863, Vol. 77 ("Neuman").

As a prefatory note, claims 9, 19, 36, and 38-42 are canceled by the present amendment, rendering the rejection of them under 35 U.S.C. § 103(a) as moot, and leaving claims 34, 35, and 37 as those still subject to the rejection.

For a rejection under 35 U.S.C. § 103(a), the cited reference(s) must teach or suggest each and every limitation in the claim(s) as issue. A further requirement necessary for a rejection

under 35 U.S.C. § 103(a) is that proper motivation must exist to combine or modify the reference(s) in the way proposed by the Examiner. As both requirements are not met in this situation, Applicant respectfully traverses the rejection and requests reconsideration.

Independent claim 34 (the sole remaining independent claims subject to the rejection) is set forth in the preceding section of this paper. Among other thing, claim 34 recites a laser system producing near infrared radiation at two specific and relatively narrow wavelength ranges, e.g., "a laser oscillator system configured and arranged to selectively emit near infrared radiation at a power density in one or both of a first wavelength range of about 865 nm to about 875 nm and a second wavelength range of about 925 nm to about 935 nm."

In contrast, L'Esperance teaches generally the use of a multi-beam laser system for application to an area of prospective surgical invasion of living tissue. Regarding the light produced by such a multi-beam laser system, L'Esperance teaches that such light: "(a) is of low-to-moderate intensity a tissue impingement and (b) is also of spectral wavelength that is preferably in the visible or in the infrared." L'Esperance, col. 2, lines, 7-10. This vague and sweeping statement of L'Esperance can encompass any wavelength beginning at about 400 nm (visible blue) and runs out to about 100,000 nm (the threshold of microwaves).

Thus, one skilled in the art would understand that this broad and general description in L'Esperance of expansive portions of the electromagnetic spectrum fails to comprehend the significance, criticality, and unexpected results of the Applicant's claimed wavelengths and ranges, i.e., (i) 870nm and 930nm, and (ii) 865nm-875nm and 925nm-935nm.

Applicant notes that MPEP § 716.02 and MPEP § 2144.05(III) set forth established case law that holding that unexpected results arising from the criticality of a claimed sub range can provide for patentability of claims reciting the sub range. Such a claimed sub range, the MPEP explains, can be patentable over prior art teaching broad ranges without comprehension of the uniqueness or unexpected results arising from the claimed sub range As Applicant has stated in the subject application, the claimed wavelengths ranges of the near infrared antimicrobial elimination system, (i) 870nm and 930nm, and/or (ii) 865nm-875nm and 925nm-935nm, are

capable of destroying/treating bacteria in an infected site "with non-ionizing optical energy and minimal heat deposition." See, e.g., paragraph [0013] of the subject application.

Thus, L'Esperance fails to comprehend the uniqueness of the Applicant's claimed wavelengths and ranges, i.e., (i) 870nm and 930nm, and (ii) 865nm-875nm and 925nm-935nm, and does not teach or suggest the use of such specific and narrow wavelength ranges for producing photodamage in bacteria in an infected site.

For the foregoing reasons, L'Esperance fails to teach or suggest at least one limitation of claim 34, 35, and 37, e.g., energizing a laser to cause the selective emission of first radiation in a first wavelength range of 865nm to 875nm and the selective emission of second radiation at a second wavelength range of 925 nm to 935 nm.

The secondary reference, Neuman, teaches the use of various near infrared (NIR) wavelengths used in the study of the deleterious effects on bacteria isolated by so-called optical traps. The reference explores a range the use of a range of NIR wavelength at extremely high power densities, e.g., on the order of 1×10^7 W/cm^2, as typically used in such optical traps, which Applicant notes typically employ beam spot sizes on the order of a micron.

Like L'Esperance, Neuman also fails to teach or suggest at least one limitation of claim independent claim, e.g., using laser radiation in one or both of two relatively narrow NIR wavelength ranges including (i) 865 nm to 875 nm and (ii) 925 nm to 935 nm, for eradication or treatment of bacteria at an infected site without detrimental heat deposition or irreversible harm to a biological system including the infected site.

Not only does Neuman fail to teach each and every limitation of the claims under rejection but the reference also teaches away from Applicant's claims, and thus there is no motivation to modify the references as proposed by the Examiner.

This is so as the Neuman reference actually teaches that the region between 870 nm and 910 "is particularly damaging and should be avoided, especially for work in vivo" and that 930

nm was "the most damaging wavelength" studied. [Emphasis added] See, e.g., Neuman, p. 2862 and p. 2859.

The Examiner cites a portion of KSR International Co. v Teleflex Inc., 82 USPQ2d 1385, 1397 (Supreme Court, 2007) for the proposition that one of ordinary skill in the art would ignore the expressed direction of the authors of Neuman (i.e., to avoid in vivo application of wavelengths around 870 nm and 930 nm) and "seeking to apply this pre-surgical sterilization method [of L'Esperance] would clearly look for wavelengths that are effective primarily against microbes which would adversely affect the sterility of the site to be sterilized."

Applicant submits that the Examiner has ***utilized hindsight reasoning to an impermissible degree*** in maintaining the rejection.

Applicant notes that Neuman was published approximately nine years after L'Esperance issued as a patent and that the Neuman article was written by five distinguished researches, including doctoral degree holders and candidates, from the Departments of Physics, Molecular Biology, Chemical Engineering, and Electrical Engineering, at Princeton University and the Princeton Materials Institute at Princeton University. The five authors of the Neuman article, which was an article published in the well-respected Biophysical Journal published by the Biophysical Society, told their peers and colleagues, by way of the article, **to avoid use of the 870 nm and 930 nm regions *in vivo***. Applicant submits that this express teaching away of Applicant's claimed wavelength ranges by the Neuman article and the lack of specific teaching of the claimed wavelength ranges by L'Esperance, i.e., by only teaching a expansive range of from 400 nm (visible blue) to 100,000 nm (the threshold of microwaves), renders the Examiner's contention of motivation as incorrect and completely untenable.

Thus, as L'Esperance and Neuman fails to teach each and every limitation of claims 34, 35, and further because at least one of these references teaches away from the Examiner's proposed modification, the cited references of L'Esperance and Neuman is an improper basis for a rejection of the claims under 35 U.S.C. § 103(a). Applicant requests the removal of the rejection accordingly.

Applicant notes that the remaining rejections of various dependent claims under 35 U.S.C. § 103(a) have been rendered moot by the cancellation of claim by the present amendment.

Provisional Claim Rejections – Double Patenting

In the Office Action, the Examiner issued provisional rejections of claims of the subject application, including remaining claims 34, 35 and 37, over five of the Applicant's co-pending applications: 11/825,550; 11/841,348; 11/981,486; 11/997,665; and, 12/019,336.

Applicant is prepared to submit one or more terminal disclaimers for the claims of this application or one or more of the noted co-pending and co-owned applications upon the issuance of claims in this application.

Conclusion

Applicant submits that the claims pending in the subject application are allowable and respectfully requests a Notice of Allowance for the application. New claims 43 and 44 are believed to be patentable at least because of their dependency on independent claim 34.

No fees are believed to be due for the submission of this paper. Please charge any fees, however, that may be due, or credit any overpayment, to Deposit Account Number 50-1133.

The Examiner is invited to telephone the undersigned attorney to discuss any aspect of the subject application or this paper.

Respectfully submitted,

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